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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,031	11/09/2000	Ushio Iwamoto	E4604	9686

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EXAMINER

KIM, SUN U

ART UNIT PAPER NUMBER

1723

DATE MAILED: 04/01/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/700,031

Applicant(s)

Iwamoto et al.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Jan 3, 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-34 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 8-34 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Filter material sealed at both ends are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Specification teaches that "A blood inlet may be located in any desired position of the case so long as blood to be treated can be fed therefrom to the outer circumferential surface side of the filter material having both ends sealed." (See page 16, line 26 - page 17, line 1).

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 8-10, 14-15, 27-29 and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,028,250 (hereinafter referred to as Loft). Loft teaches a filter device comprising a coiled core with hollow center (16) and comprising filter material made of two layer of sheets (22, 23) bonded to each other to form a blood filter layer and a mesh-like spacer layer (25) rolled from inner side of the blood filter layer around the hollow center and a

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casing (10) having an inlet (11) in fluid communication with an outer circumference of the blood filtering layer of the coiled core and an outlet communicating with the hollow center (16) wherein a length of the coiled core is about 7 times the outer diameter of the coiled core according to the figure 1 for module 10 (see figures 1-5; col. 2, lines 22-54; col. 3, line 49 - col. 5, line 59).

5. Claims 16-17 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,266,195 (hereinafter referred to as Hopkins). Hopkins teaches a filter device comprising a coiled core with hollow center (37) and comprising filter material made of a membrane envelope (15) as a blood filter layer and a spacer layer (17) wherein outer side of the spacer layer is an outer circumference of the coiled core and the blood filter layer surrounds the hollow center (37) and a casing (10) having an inlet (67) in fluid communication with an outer circumference of the blood filtering layer of the coiled core and an outlet (35) communicating with the hollow center (37) (see figures 1-3; col. 3, line 64 - col. 4, line 55; col. 6, line 28 - col. 8, line 23).

6. Claims 12, 20 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loft as applied to claims 8, 16 and 27 above, and further in view of U.S. Patent No. 4,872,990 (hereinafter referred to as Van Wijk). Claims 12 and 30 essentially differ from Loft in reciting that the spacer layer thickness is not less than 0.5 mm and not more than 2.0 mm. Van Wijk suggests that width dimension of the rods measured perpendicular to the membrane layers i.e. spacer thickness is 0.5 mm to 2.5 mm in a coiled filtration module wherein such spacer thickness do not cause blockage of flow and provide favorable ratio between membrane surface and module

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volume (see col. 1, line 64 - col. 2, line 44). It would have been obvious to a person of ordinary skill in the art to modify the thickness of spacer in Loft to be not less than 0.5 mm and not more than 2.0 mm to improve flow of fluid and provide favorable ratio between membrane surface and module volume.

7. Applicant's arguments with respect to claims 8-34 have been considered but are moot in view of the new ground(s) of rejection.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 4,022,692 and 4,834,881 and 4,253,962 teach various filters with spirally wounded filter and spacer material.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

  
John Kim  
Primary Examiner  
Art Unit 1723

J. Kim  
March 24, 2003